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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,786

Applicant(s)

MAJOR ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 14-25 and 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12, 13, 26-28, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/12/01, 3/12/03, 4/28/04
9/24/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 1-4, 12-13, 26-28 & 33-34) in the reply filed on 10/22/04 is acknowledged. The traversal is on the ground(s) that there is a "lack of a showing that examining claims of Groups I-III would an undue burden". This is not found persuasive because the multipotent cells of Group III are transfected with DNA constructs, which are not required for the multipotent neural cells of Group I, and in which the Group II cells derived from the multipotent cells of Group I are at a different developmental stage (e.g., neurons or glial, etc.) and are therefore no longer multipotent; thereby, possessing different characteristics and properties when compared to the multipotent neural cells of Group I. Moreover, as previously made of record, because Major et al (US Patent 5,753,491) teach a CNS immortal and multipotent neural cell line, which meets the recited claim limitations, no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Again, note that PCT Rule 13 does not provide for multiple products or methods within a single application. The requirement is still deemed proper and is therefore made FINAL.

Claims 5-11, 14-25 & 29-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/22/04.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Therefore, the first sentence of the specification should be amended to: **This application is the National Stage of International Application No.**

PCT/US00/06940, filed 3/17/01...

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 12-13, 26-28 & 33-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 & 16 of U.S. Patent No. 5,753,491. Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic isolated CNS immortal multipotent cell lines of the instant invention reasonably comprise a pharmaceutically acceptable/sterile carrier, in order to keep them viable. Therefore, the cell compositions of '491 comprising immortalized human fetal neuro-glial cells are reasonably equivalent to (i.e., claim 2), or a species of the immortal CNS multipotent neural stem cells of the instant invention, because all of these cell lines are multipotent, and therefore, can "differentiate toward a neuronal cell or a glial cell", by definition, and in which any intended use recited in '491 carries no patentable weight.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 12-13, 26-28 & 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Major et al (U.S. Patent 5,753,491; IDS Ref #2).

Major et al disclose isolated, immortalized CNS human fetal neuro-derived cell lines, which “generally produce progenitor neuronal and glial cells” (e.g., column 7, lines 22-37); thereby, being multipotent, by definition (i.e., as it relates to claims 1-3, 12 & 33). Cells derived from SVG cells are also described by Major (e. g., column 4, lines 66 - column 5, line 1; column 7, lines 57-65), which further appear identical to those cells (i.e., multipotent cells) described on pgs 3 & 15-17 of the instant specification (i.e., as it also relates to claims 1-3, 12 and 33). In that all of these cells described by Major et al reasonably appear identical to the alternative names of “NG1, NG2 and NG3” cells recited in claim 13, and inherently express markers that uniquely define what constitutes a multipotent stem cell, the limitations of claims 4 and 13 are met; absent evidence to the contrary. Finally, in that the process of producing multipotent neural

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stem cells does not materially change the multipotent neural stem cell product produced, the limitations of claims 26-28 and 34 are anticipated.

5. Claims 1-4, 12-13, 26-28 and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Weiss et al (U.S. Patent 5,750,376; IDS Ref #3).

Weiss et al disclose isolated human CNS multipotent neural stem cell lines (i.e., neurospheres; as it relates to claims 33-34), which are clonally-derived/ "immortalized" and have the "potential to differentiate toward a neuronal cell or a glial cell" (e.g., column 11, lines 49-56) columns 13, 17-18, 21-22, 36 and 48; as it relates to claims 1-3 and 12). In that the multipotent stem cells described by Weiss et al reasonably appear identical to the alternative names of "NG1, NG2 and NG3" cells recited in claim 13, and inherently express markers that uniquely define what constitutes a multipotent neural stem cell (e.g., column 56), the limitations of claims 4 and 13 are met; absent evidence to the contrary. Finally, in that the process of producing multipotent neural stem cells does not materially change the multipotent neural stem cell product produced, the limitations of claims 26-28 and 34 are anticipated.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
January 25, 2005

ROBERT C. HAYES, PH.D.
PATENT EXAMINER